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What You Need to Know Before Getting an Implant or Hip Device

Analysis by Dr. Joseph Mercola Fact Checked | June 02, 2022

STORY AT-A-GLANCE

- In 2019 Europe's medical device industry was so poorly regulated that U.S. regulators compared it to a system where "patients are treated like guinea pigs;" three years later, the devices fall under new regulations "evaluating the quality, safety and efficacy" of the products
- Faulty medical device implants, including artificial spine disks, breast implants, hip replacement devices, bone graft devices and insulin pumps have caused serious health problems
- Medical device implants in Europe are not regulated as strictly as medications and therefore often undergo little or no safety testing
- Medical device makers set up shop in Europe where they can get their products approved simply and cheaply
- Medical device manufactures are legally required to report problems that damage people's health, but they often don't and face no penalties

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A 2019 documentary, "Shady Implants: The 'Guinea Pigs' of the Medical Industry," exposed corruption in the medical device industry. The film, produced by German Public

Broadcast Service DW, revealed that the number of health problems associated with medical devices had risen significantly through the years.

This is strongly tied to a lack of government regulation, particularly in Europe, where medical device manufacturers were getting away with bringing potentially harmful products to market without conducting adequate safety testing. Fortunately, reforms have been initiated in Europe since the documentary, effective in May 2021, that are aimed to better regulate the industry.[1]

However, in addition to sidestepping product safety testing, medical device manufacturers have been caught paying surgeons big bucks to use their products, as well as encouraging them to recommend the medical devices to their colleagues. The business model is similar to the pharmaceutical industry in the U.S., which often markets drugs to doctors by offering them perks such as free meals and travel.

The featured film reveals that a number of different medical devices have been linked to serious health problems. Some of these devices include artificial spine disk implants, breast implants, hip replacement devices, bone graft devices and insulin pumps.

The health problems linked to defective medical devices are often very severe and have resulted in sterility, paralysis, cancer, chronic pain and death. Even more disturbing is that patients report having no knowledge of these potential health risks.

‘It’s an Absolute Disaster. This Never Should Have Happened’

In the film, the first example of someone harmed by this act of gross negligence is Thomas Woska. He tells the film’s producers that he had an artificial disk implanted in his back that disintegrated into lots of tiny plastic pieces. His back is now full of plastic scrap from the defective device, and it’s extremely difficult to have removed. He is in so much pain he can no longer work.

Woska is one of 113 patients in Germany who received the defective artificial disk. Two-thirds of those patients had to undergo additional major surgeries to correct the damage caused by the defective disk.

The film shows Wosk visiting Dr. Karsten Ritter-Lang, a specialist in orthopedic and trauma surgery at STENUM Orthopedic Clinic in Ganderkesee, Germany. Ritter-Lang, who has treated dozens of patients harmed by complications from the defective disk implants, said:

> *"They are in a lot of pain. First of all, there's the actual physical discomfort caused by the defective disk. And then, there's the psychological distress, because they know they've got this ticking timebomb in their body."*

The corrective surgery that Wosk needs is a dangerous one. Trying to remove the tiny bits of plastic, some of which have become lodged behind Wosk's spine, carries a risk of accidentally cutting in to vital organs and blood vessels.

The shattered device severely damaged his vertebrae, and removing it is like pulling out old pieces of chewing gum, says Ritter-Lang. It's an absolute disaster. This never should have happened, he adds.

Medical Device Maker Ignores Problems in Animal Studies

The spinal implant that Wosk received was manufactured by Ranier Technology, based in Cambridge, England. The company is one of thousands of small businesses in Europe trying to make it big in the medical device market.

Ranier tested the plastic disks on baboons, and the results were later leaked by a whistleblower. The film shows Ritter-Lang reviewing the animal test results, which showed serious problems with the disks. He says:

> *"It's clear from these studies that the implants did not become properly integrated into the spinal system. Later, I noticed similar complications in my patients who had been given these disks."*

Ranier ignored red flags about its spinal disk implants. Shockingly, it continued to the next phase of the approval process and began performing clinical tests on humans. Ranier tested the product on people for three short months before it received approval

from the British Standards Institution (BSI) for two implants, Cadisc-L and Cadisc-C. The BSI did not consider the animal studies or the brevity of the human clinical trials.

Defective Spinal Disk Left One Man Sterile, Unable to Work

Twenty-nine people signed up for the disk surgery. One of them was Andreas Rode, a butcher who enjoyed boxing. In 2010, he was suffering from a herniated disk, for which his doctor recommended an implant. Although the disk had not yet been officially approved, he agreed to the surgery in hopes it would resolve his pain.

Rode felt fine after the surgery. But just like what happened to Wosk, the plastic disk broke apart. It did not integrate into his body like it was supposed to. Rode had to have emergency surgery to remove the tiny pieces of plastic that had broken away from the disintegrating disk.

He needed several more operations to remove the plastic. His outcome was catastrophic. Rode can no longer have children and he can't work as a butcher anymore, nor can he box. His nerves are damaged and he is physically incapacitated. Rode says all he wants is for someone to admit they made a mistake, but he doesn't see that happening any time soon.

Ranier Technology Files for Bankruptcy

While Rode lay in the hospital recovering, doctors in Germany continued to use the plastic disks. The German government received many reports about serious reactions to the devices, but for years it never did anything to stop the disks from being sold.

A head physician at one of the clinics who was using the plastic disks was later fired for accepting illegal payments from Ranier. The British manufacturer has since filed for bankruptcy.

The Guardian reported in 2018 that Ranier sought approval for its spinal disk in Europe because the process was easier than in the U.S. Like many medical device makers,

Ranier hoped getting approval in Europe would help fast-track approval in the U.S. A large body of research on defective medical devices known as the Implant Files, reported:[2]

> *"Like Cadisc-L, the regulatory strategy for Cadisc-C is to penetrate Europe first and follow up in the USA … On the whole the regulatory process and required testing tends to be more stringent in the US compared with the EU."*

Faulty Medical Devices Killed 83,000 in the U.S. in 10 Years

Between 2015 and 2018, regulators in the U.K. received 62,000 reports of adverse reactions to medical devices, according to a 2018 report by the Guardian.[3] A third of those cases resulted in serious health problems, and 1,004 of them died.

Meanwhile in the U.S. the FDA received 5.4 million "adverse event" reports in just one decade. Injuries were reported in 1.7 million cases, and 83,000 people died. Nearly 500,000 underwent additional surgery to remove the device.

The data, which make up the Implant Files, are derived from 252 journalists and 59 media organizations across 36 countries that uncovered major problems with medical devices, an industry that totals $400 billion worldwide.

Breast implants are another medical device linked to health problems. By 2018 alone, an estimated 500,000 women globally have been affected by defective breast implants made of cheap industrial silicone, the same type of silicone used to seal windows, according to the film. In 2019, the FDA decided to hold a hearing where dozens of women testified about breast implants had either caused cancer or some other debilitating medical problem.[4]

The implants are made of a textured, Velcro-like surface that attaches to the breast tissue. They have been linked to anaplastic large cell lymphoma, a rare form of Non-Hodgkin lymphoma that affects the immune system. And, in 2022, breastcancer.org[5] reported that:

"The FDA has long advised women considering breast implants that they shouldn't expect them to last a lifetime, and should assume they'll need additional surgeries at some point because of well-known complications like capsular contracture (tightening of the capsule of scar tissue around the implant) and implant rupture.

But there are also two serious risks that recently started to receive more attention from health authorities, doctors, and the media because of new research and because women who were affected are speaking out.

One is … breast implant illness (BII) — a cluster of symptoms such as fatigue, memory loss, and joint pain that can occur after getting breast implants and that frequently improve after the removal of the implants (explantation). The other … is a rare form of T-cell lymphoma (cancer of the immune system) called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) that develops in the scar tissue and fluid surrounding an implant."

Defective Breast Implant Maker Convicted of Aggravated Fraud

In 2019 the Times reported that since 2015, 1,200 women in the U.K. had been seriously harmed by the defective implants.[6] Complications with the implants were reported across Europe and in the U.S. and Canada. A series of investigations by the International Consortium of Investigative Journalists found that a poor design and a lack of safety testing are what led to health problems in patients.

Poly Implant Prothèse was one of the manufacturers of the textured breast implants. It was accused of selling hundreds of thousands of defective breast implants in 65 countries. A lawsuit against the company resulted in a conviction of aggravated fraud for its founder, Jean-Claude Mas, as well as four former employees, according to a report by The New York Times.[7]

Prosecutors in the case accused Mas of using a gel for the breast implants that was seven times cheaper than an alternative, and testing showed the company's breast

implants ruptured more easily than others. Around 7,000 women have sued Poly Implant Prothèse for damages. The company was accused of ruining thousands of lives, and using women as lab rats.[8]

EU Warned Years Ago of Medical Devices' Serious Threat

For at least a decade, some officials in the EU warned about the dangers posed by medical devices. Dagmar Roth-Behrendt, former Germany MEP and special adviser to the EU Commission for Health and Food Safety, has called for more studies and better testing for medical devices.

Unfortunately, her efforts have been met with opposition from the medical device industry. Roth-Behrendt says medical devices should be regulated similarly to medications and be subjected to stricter quality control measures before receiving market approval. In the film she says:

> *"The problem is that the certification agencies are privately run, not government run. That's led to a kind of business tourism, where companies come to Europe where they can get certifications for their products quickly and cheaply.*
>
> *That's bad enough for a hairdryer or a mixer. People want those products to be safe so that they don't explode when they use them. But what about medical products that are placed inside your body? If something goes wrong with them, they can cause serious physical damage."*

Medical device manufactures are fighting that proposal. They think the current regulations are enough to keep people safe and that stricter laws would threaten hundreds of thousands of industry jobs.

Journalist Shows How Easy Medical Device Approval Is

In 2014, a Dutch journalist showed how easy it was to get approval for a medical device in Europe. In the film she says:

> *"We're designing a device that's not safe at all, a mesh implant that helps to stabilize the uterus. We found all the component parts at the supermarket, and took some photos. Now it's ready to go."*

Because similar products are already on the market, the journalist did not need to sign up for human clinical trials. Up to 90% of high-risk medical devices do not have to undergo medical trials, she says. The journalist made an appointment at a certification center in Vienna, Austria, where they filmed the meeting with a hidden camera.

To their astonishment, the secret film shows that the official doesn't care to see the actual product itself. Instead, he relies on the documents provided by the journalist. No doctors are present during the meeting. The undercover video shows the approval officer saying, "There is a clinical necessity, there is clinical evidence, there are well-known materials, so why not?"

Device Makers Favored Europe's Simple, Cheap Approvals

Under this lax approval process, Europe approved more than 500,000 medical devices,[9] but U.S. officials have criticized Europe's regulatory process for doing so. One congressman went as far as to say that in Europe, "patients are treated like guinea pigs." Manufacturers in Europe are legally required to report problems that damage people's health, but they often don't and face no penalties.

Another manufacturer caught selling defective products was Medtronic, the world's largest medical device maker. In 2018, it agreed to a $43 million settlement with investors over allegations it made improper payments to surgeons to cover up problems with a bone graft product. Investigative journalist Paul D. Thacker says Medtronic's business model is to pay doctors to put devices in people or to recommend their device to other doctors.

Medtronic's bone graft product, Infuse, caused dangerous side effects in patients who had spine infusion surgery. Some of the side effects include nerve injury, increased pain, numbness, paralysis and additional surgery.

Medtronic Infuse Product Leaves One Patient Paralyzed

Medtronic's Infuse product left Stefanie Clair paralyzed from the chest down. Clair says she had no idea of the risks posed by Infuse. An investigation later found that Medtronic purposely tried to downplay the risks of its Infuse product. Dr. Eugene Carragee, professor of orthopedic surgery at Stanford University Medical Center, said:

> *"The complications of Infuse weren't trivial, they were catastrophic, cancer, sterility, life-threatening airway events."*

Medtronic also manufactured an unknown number of defective insulin pumps that caused harm and death in some patients. Germany's faulty reporting system made it impossible to know how many incidents there were involving the defective insulin pumps.

Despite the problems, Germany continues to use private inspection companies, and attempts to reform this system have been rejected by the government.

Defective Hip Implants

Jurgen Thomas, a technical manager at a wine cellar, had hip replacement surgery. But four years later the device, which had titanium components, had to be removed. The hip implant rubbed against nearby bones, causing metal scraps to break off and end up in the surrounding tissue.

He suspected that the device had not been properly tested, so he filed a lawsuit against the manufacturer, Zimmer Biomet.

Seven hundred people received the defective hip implants. Some filed lawsuits that have been dragging on for years. Attorneys for Zimmer Biomet tried to pin the blame on the surgeons, and even some of the patients. Tim Abele received one of the defective hip implants. The harm caused by the device has hindered his ability to walk more than 500 yards at a time. He also lost his sense of taste and smell.

Investigation Finds Hip Implants Were Not Safety Tested

The plaintiffs suspected Zimmer Biomet knew about the problems with its hip implant. An investigation ordered by the court revealed Zimmer Biomet failed to properly test the implant. Yet it still qualified for certification by submitting tests from a similar but old device. Product testing expert Wolfram Mittelmeier said:

> *"If we were talking about the automobile industry, it would be difficult to compare one model of the same car with a newer model because the newer design would include some modifications."*

Sure enough, the investigation found the hip replacement defective because it rubbed against the surrounding bone structure. It's a complication that would have been identified had the manufacturer done the proper safety testing. Even more disturbing is that these health risks had already been widely reported, including in research publications as early as 2003.

On October 15, 2018, a judge ruled that Zimmer Biomet's hip implants should never have been approved for sale because the health risks were well-known and more testing should have been done.

The judge ordered Zimmer Biomet to pay Thomas 25,000 euros in damages. However, the manufacturer maintains their devices were not faulty and is expected to appeal, dragging out the case even longer.

The film concludes by speaking with an auditor who has worked for various medical device certifiers, who says he has serious concerns about how quality control measures are conducted on various medical devices. One of the problems is that many of the auditors are freelancers and don't have the expertise to make qualified judgments, he says, adding:

> *"None of them is really independent. They almost never decide that a product is risky. If they did, the testing company could get into trouble, and they might lose their job."*

European Law for Medical Devices Doesn't Go Far Enough

In spite of these obstacles, things are beginning to change, at least somewhat, in Europe's medical device industry. In 2017, Europe approved new regulations on medical devices that include more clinical studies, more controls and an independent database.[10] But the new law does not change the root of the problem, which is a lack of independent product testing.

The new rules were set to go into effect in 2020, but the industry lobbied hard to delay that deadline. Sadly, Roth-Behrendt concedes in her efforts to create a state agency that would have imposed stricter controls on medical device testing. She says in the film:

> *"I wanted to draft legislation that would make sure the devices are safe for the patients, and would allow the companies to make money. But the new law doesn't do that.*
>
> *It still makes me angry after all these years. It's like a wound that won't heal. I'm upset that we weren't able to make life safer for the around 741 million people who live in the EU. I feel as though I failed, and I take responsibility for that. I'm ashamed of myself and my colleagues. It makes me so mad that I almost want to cry."*

In the U.S. in 2022, more than 80,000 deaths and 1.7 million injuries have now been recorded in the past decade, according to The Regulatory Review[11] — and the problem "will only worsen unless proposed reforms place pressure on FDA," they quote a law student, William Chanes Martinez, of predicting.

Since the manufacturers have incentives to churn out devices as quickly as possible, jn essence, it's time to stop the madness, he adds:

> *"… in the absence of adequate regulation, FDA should take several actions: reinstate requirements for manufacturers to publish all medical device approvals and their supporting rationales; extend mandatory medical device-related reporting to all medical professionals who use medical devices in their*

practice; and eliminate its Voluntary Malfunction Summary Reporting program, which gives manufacturers discretion to report certain device malfunctions instead of requiring disclosure."

Sources and References

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